Wyeth

February 14, 2006

The purpose of this letter is to express Wyeth's opposition to the passage of the following bills being considered by the Michigan House of Representatives:

- H.B. 4044 – A repeal of the immunity from liability for drugs that have been approved by U.S. Food and Drug Administration (FDA).
- H.B. 4045 – A bill that would allow the repeal provided in H.B. 4044 to be retroactive to January 2, 1996.
- H.B. 4046 – A bill to expand the consumer protection act to include liability for inaccurate representations concerning risks of certain drugs, medications, and supplements.

As a global leader in pharmaceuticals, consumer health care products, and animal health care products, Wyeth is opposed to these bills because they threaten to undermine the authority of the U.S. Food & Drug Administration (FDA), they can have detrimental effects on the ability of the pharmaceutical industry to bring new medications to market, and they raise significant constitutional concerns.

The FDA oversees one of the most comprehensive drug approval systems in the world. The agency is responsible for controlling nearly every step in the development and marketing of prescription drugs in the United States. From the earliest clinical testing all the way through to the specific labeling for each product, the FDA's team of scientists and physicians are charged with assuring the safety and efficacy of prescription medications sold to U.S. consumers.

In 1996, after careful consideration, the Michigan Legislature recognized that pharmaceutical manufacturers should be immune from liability when their prescription medications undergo the rigorous drug approval process of the FDA. Understanding that circumstances may exist where such immunity is not warranted, the legislature included provisions allowing suits to proceed if it is determined that the drug company willfully withheld or misrepresented information during the approval process. This law strikes an appropriate balance by allowing the FDA to do its job, while punishing companies that do not act in good faith.

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The passage of H.B. 4044 undermines the FDA's authority by replacing the rational, science-based regulation of drugs with judgments made by juries who may be driven by sympathy over fact. The men and women of a jury would be asked to make scientific determinations that trump those of the physicians and clinicians employed by the FDA. Juries are placed in the unenviable position of assessing scientific evidence and reaching a dispassionate judgment in the face of an injured plaintiff.

The passage of the referenced bills will also impact Wyeth's ability to bring new and innovative treatments to market by diverting resources from research and development (R&D) to defending our FDA-approved products in court. With R&D programs focused on small molecules, vaccines and biotechnology, Wyeth is exploring more than 60 new therapies for medical conditions such as diabetes, breast cancer, multiple sclerosis, HIV, Alzheimer's disease and schizophrenia. The inordinate costs associated with defending claims in court and the potential judgments associated with these claims require that difficult business decisions be made with regard to funding R&D projects. It is in the best interest of patients that pharmaceutical manufacturers be able to dedicate their financial resources to developing innovative new medicines instead of defending products that have undergone a thorough approval process.

Lastly, the passage of H.B. 4045 would create new liability for conduct that was previously protected. The existing FDA defense was designed to protect companies in the arena of product liability, which can inhibit the development and introduction of new products. H.B. 4045 would reach back in time to remove this certainty and protection. This retroactive removal of protection – to create wide-ranging new liability for past conduct – presents serious constitutional questions under the Michigan and United States Constitutions

For the reasons stated above, Wyeth opposes the passage of House Bills 4044, 4045, and 4046 and we respectfully request that they not be approved by the Michigan House of Representatives.